

Applicant: Cornelius, et al.
Serial No.: 10/792,111
Group Art Unit: 3739

PATENT
Docket No.: 21947-304

REMARKS

This Amendment is filed in response to the Official Action dated June 15, 2005. In this Amendment, independent claims 24, 37 and 43 are amended, new dependent claims 51-55 are added and dependent claims 25-30, 38-42 and 44-50 are unchanged. Following entry of this amendment, claims 24-30 and 37-55 shall be pending.

In the Office Action, claims 24-30 are rejected as being indefinite, and claims 24-30 and 38-50 have been rejected based on prior art grounds. The applicants hereby request reconsideration of these claims in view of the reasons set forth below.

I. REJECTIONS UNDER 35 U.S.C. SECTION 112

The Examiner rejected claims 24-30 as being indefinite on grounds that "the claimed phrase 'expandable electrode arms' is inconsistent with the specification, which reads 'retractable electrode arms.'" In this regard, it is not clear if the rejection is based on the assertion that the claim terms must exactly match that used in the specification or on the assertion that terms "expandable electrode arms" and "retractable electrode arms" are somehow inconsistent to describe the same element of the present invention. In either event, the Applicant traverses the rejection for at least the reasons set forth below.

Regarding the first assertion, Applicant notes Section 2173(e) of the MPEP which states:

The mere fact that a term or phrase used in the claim has no antecedent basis in the specification disclosure does not mean, necessarily, that the term or phrase is indefinite. There is no requirement that the words in the claim must match those used in the specification disclosure. Applicants are given a great deal of latitude in how they choose to define their invention so long as the terms and phrases used define the invention with a reasonable degree of clarity and precision.

Hence, clearly the Applicant is not required to use the exact wording in the claims as is used in the specification. In fact, the Applicant need only use terms and phrases that

Applicant: Cornelius, et al.
Serial No.: 10/792,111
Group Art Unit: 3739

PATENT
Docket No.: 21947-304

define the invention with a reasonable degree of clarity and precision. In this respect, the Applicant submits that the phrase "expandable electrode arms" meets this "reasonable degree of clarity and precision".

With regard to the second assertion, the Examiner is correct that the arm elements of one embodiment of the invention are described as being retractable, e.g., the retractable electrode arms 408 depicted in Figures 22A – 26A. However, as seen in other embodiments, e.g., in Figures 22A-26A and paragraphs [0117]-[0135], the "retractable electrode arms 408" are also described and depicted as spreading out at an angle during extension to a fully deployed position. Figures 22A-22C, for example, illustrate this progression insofar as Figure 22A shows a retracted and compressed state and Figures 22B and 22C show an extended, expanded state. See also the text in Paragraph [0119]. Thus, the Figures and specification demonstrate that there is nothing inconsistent in reciting the arms as being "expandable" in the claims while at the same time describing in the specification that the arms are also retractable.

Therefore, it is submitted that the above discussion adequately demonstrates the definiteness of claims 24-30 under the applicable standards of 35 USC Section 112. It is therefore requested that this rejection be withdrawn.

II. REJECTIONS UNDER 35 U.S.C. SECTION 102

Claims 24, 25, 37, 38, 43, and 44 are rejected under 35 U.S.C. Section 102(b) as being anticipated by U.S. Patent No. 5,980,519 to Hahnen et al. (*The Hahnen Patent*). For at least the reasons set forth below, this rejection is traversed.

The presently claimed invention as set forth in Independent claim 24 is directed to a novel positioning device for an ablation tool that includes at least two expandable electrode arms and a flexible conforming strip extending between the at least two expandable electrode arms; the flexible conforming strip having sufficient flexibility so as to substantially readily conform to the shape of a target ablation site upon contact of the conforming strip with the target ablation site; and an ablation mechanism included on the conforming strip. In this Amendment, the presently claimed invention has been

Applicant: Cornelius, et al.
Serial No.: 10/792,111
Group Art Unit: 3739

PATENT
Docket No.: 21947-304

further defined to recite that the flexible conforming strip is more flexible than each of the at least two expandable electrode arms.

The *The Hahnen Patent* cannot be properly relied upon as anticipating the invention as recited in amended claim 24. For example, at a minimum, *The Hahnen Patent* fails to show a flexible conforming strip extending between at least two expandable electrode arms or a flexible conforming strip that is more flexible than the at least two expandable electrode arms as currently claimed.

In this regard, the Examiner refers to Figure 4 and asserts that elements 184a and 184b of *The Hahnen Patent* represent at least two "expandable electrode arms" and that element 199 is a "flexible conforming strip" extending between the two arms. In fact, however, the elements 184a and 184b and 199 are simply different regions of a uniform continuous coiled loop of wire (See Column 4, lines 28-36), not the structure as claimed. Moreover, the very nature of this uniform continuous coiled loop of wire prevents the region 199 (asserted to be the "flexible conforming strip") being more flexible than the regions 184a and 184b (asserted to be the "expandable electrode arms") as now claimed. In other words, *The Hahnen Patent* simply teaches a coiled loop of uniform continuous wire that has the same apparent flexibility in all of its regions. This is inapposite to the claimed invention.

As depicted in one embodiment in Figures 22A-22C, the invention includes at least two expandable electrode arms 408 that are distinct from the flexible conforming strip 410. As is also seen, the flexible conforming strip has more flexibility than the electrode arms 408. It is the distinct nature of the electrode arms and the conforming strip and the resulting higher flexibility of the conforming strip that allows this strip to be precisely positioned at a target location, for example, as described in Figures 22A-22C and their accompanying description in the specification.

That the loop 118 of *The Hahnen Patent* does not provide the same accuracy and precision as the claimed invention is evident when comparing the coil loop 118 of Figure 3 to other disclosed embodiments in *The Hahnen Patent*. For example, Figures 6, 9b, 10b, 11 of *The Hahnen Patent* all show the coil loop being wound around a

Applicant: Cornelius, et al.
Serial No.: 10/792,111
Group Art Unit: 3739

PATENT
Docket No.: 21947-304

"shaped head". This "shaped head" provides the necessary reinforcing structure to the loop so that the loop can be more precisely and directly positioned at the ablative site. Thus, the disclosure of the "shaped head" appears to be instructive that the coil 118 of Figure 3 does not provide the same degree of accuracy and precision as those that rely on a shaped head to control the coil placement.

Thus, for at least the reasons stated above, it is submitted that *The Hahnen Patent* fails to anticipate claim 24. It is also submitted that the *The Hahnen Patent* does not render claim 24 obvious.

Turning to claim 25, this claim depends from claim 24 and thus for at least the above reasons is also novel and unobvious over the cited prior art. However, this claim further limits the claimed invention and thus is separately patentable over the cited prior art.

Turning next to Independent claim 37, this claim is directed to a method of positioning an ablation tool within a body, which includes providing an ablation tool having an elongated body and a flexible electrode disposed between at least two arm members on a distal end of the ablation tool and wherein the flexible electrode is more flexible than the at least two arm members. As with Independent claim 24, *The Hahnen Patent* cannot be properly relied upon as anticipating claim 37.

As discussed above, *The Hahnen Patent* shows neither a flexible electrode disposed between at least two arm members nor a flexible electrode that is more flexible than the at least two arm member. Thus, for at least all the same reasons, it is submitted that *The Hahnen Patent* fails to anticipate claim 37. It is also submitted that the *The Hahnen Patent* does not render claim 37 obvious.

Turning to claim 38, this claim depends from claim 37 and thus for at least the above reasons is also novel and unobvious over the cited prior art. However, this claim further limits the claimed invention and thus is separately patentable over the cited prior art.

Applicant: Cornelius, et al.
Serial No.: 10/792,111
Group Art Unit: 3739

PATENT
Docket No.: 21947-304

Turning next to independent claim 43, this claim is directed to an ablation positioning device that includes a first arm member disposed on the distal end of an elongated member; a second arm member disposed on the distal end of the elongated member; and a flexible ablation member extending between the first arm member and the second arm member, wherein the flexible ablation member is more flexible than said first arm member and said second arm member. As with independent claim 24, *The Hahnen Patent* cannot be properly relied upon as anticipating claim 43.

As discussed above, *The Hahnen Patent* shows neither a first arm member disposed on the distal end of an elongated member; a second arm member disposed on the distal end of the elongated member; and a flexible ablation member extending between the first arm member and the second arm member, nor a flexible ablation member that is more flexible than said first arm member and said second arm member. Thus, for at least the same reasons, it is submitted that *The Hahnen Patent* fails to anticipate claim 43. It is also submitted that *The Hahnen Patent* does not render claim 43 obvious.

Turning to claim 44, this claim depends from claim 43 and thus for at least the above reasons is also novel and unobvious over the cited prior art. However, this claim further limits the claimed invention and thus is separately patentable over the cited prior art.

II. REJECTIONS UNDER 35 U.S.C. SECTION 103

Claims 26-30, 39, 41-42 and 45-47 are rejected under 35 U.S.C. Section 103(a) as being obvious by U.S. Patent No. 5,980,519 to Hahnen et al. (*The Hahnen Patent*) in view of U.S. Patent No. 6,558,382 to Jahns et al. (*The Jahns Patent*). For at least the reasons set forth below, these rejections are traversed.

In this regard, these claims various depend from one of independent claims 24, 37 and 43 and thus the Examiner is referred to the arguments above presented in regard these independent claims. For example, with respect to claim 24, *The Hahnen Patent* discloses neither at least two expandable electrode arms and a flexible

Applicant: Cornelius, et al.
Serial No.: 10/792,111
Group Art Unit: 3739

PATENT
Docket No.: 21847-304

conforming strip extending between the at least two expandable electrode arms nor a flexible conforming strip that has more flexibility than the at least two expandable electrode arms. However, these claims further define and describe the invention and thus are separately patentable.

In a further example, however, it is submitted that *The Hahnen Patent* has been improperly combined with *The Jahns Patent* at least with respect to claims 27, 42 and 46. Although *The Jahns Patent* may show bipolar needle electrodes, these bipolar electrodes cannot be simply placed on the flat electrode embodiment of the *The Hahnen Patent* as the Examiner claims. As their name implies, bipolar electrodes have either positive or negative polarity. To achieve this, each electrode must have connections so that each of the plurality of electrodes can produce either positive or negative polarity, completing the ablative circuit. However, as seen in column 7, lines 61-64 of *The Hahnen Patent*, "the solid portion 1119 may be in the form of flattened stock (shown), wire, or cable and is preferably made of a high temperature spring material, such as nitinol, nichrome, titanium, or nickel- or cobalt-superalloy." In other words, this flattened stock is still part of the ablative loop and therefore is simply a single, exposed, electrically-conductive wire. Therefore, adding the electrodes of *The Jahns Patent* to this flattened stock would merely create a mono-polar loop with conductive pins, not a series of bipolar electrodes as the Examiner claims. Additionally, even if the flattened stock could somehow internally accommodate the bipolar electrodes, the diameter of the loop wire would likely be too large to allow retraction of the loop within the tool. Therefore, for at least these reasons, it is further submitted that the rejection is improper.

Claims 40 and 48-50 are rejected under 35 U.S.C. Section 103(a) as being obvious by U.S. Patent No. 5,980,519 to Hahnen et al. (*The Hahnen Patent*) in view of U.S. Patent No. 6,558,382 to Jahns et al. (*The Jahns Patent*) in further view of U.S. Patent No. 6,558,382 to Lundkvist et al. (*The Lundkvist Patent*). For at least the reasons set forth below, it is submitted that these prior art rejections should be withdrawn and the pending claims allowed.

Applicant: Cornelius, et al.
Serial No.: 10/792,111
Group Art Unit: 3739

PATENT
Docket No.: 21947-304

Claims 40 and 48-50 depend from independent claims 37 and 43, respectively and thus the Examiner is referred to the arguments presented in regard to claims 37 and 43 above. For example, *The Hahnen Patent* discloses neither a flexible electrode disposed between at least two arm members nor a flexible electrode that is more flexible than the at least two arm members as discussed above. However, these claims further define the present invention and thus are separately patentable.

II. NEW DEPENDENT CLAIMS 51-55

New dependent claims 51-55 are added in this application. These claims are dependent from Independent claim 37. These claims are directed to a feature of the present invention whereby a continuous line of ablation is created by "walking" the flexible electrode. Support for these claims may be found in the present application in Figures 24A-D and Paragraph 0126 (as numbered in the published application). No new matter is introduced. Being dependent from Claim 37, these new claims are allowable for at the reasons set forth above with respect to Claim 37. However, these new claims further define and describe the present invention and thus are separately patentable beyond Claim 37.

Applicant: Cornelius, et al.
Serial No.: 10/792,111
Group Art Unit: 3739

PATENT
Docket No.: 21947-304

CONCLUSION

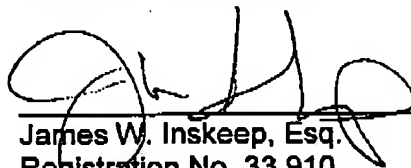
In view of the foregoing, it is submitted that pending claims 24-30 and 37-55 are now in condition for allowance. Hence an indication of allowability is hereby requested.

If for any reason direct communication with Applicants' attorney would serve to advance prosecution of this case to finality, the Examiner is cordially urged to call the undersigned attorney at the below listed telephone number.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-2809.

Respectfully submitted,

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